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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,572	05/14/2004	Itzhak Bentwich	050992.0202.01USCP	3571
37808	7590	01/24/2008	EXAMINER	
ROSETTA-GENOMICS			WOLLENBERGER, LOUIS V	
c/o PSWS			ART UNIT	PAPER NUMBER
700 W. 47TH STREET			1635	
SUITE 1000			MAIL DATE	DELIVERY MODE
KANSAS CITY, MO 64112			01/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/709,572

Applicant(s)

BENTWICH ET AL.

Examiner

Louis V. Wollenberger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 25-38 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Specification/Sequence Compliance***

Applicant's response filed 12/2/2007 is acknowledged. The objection to the disclosure is because of an invalid sequence listing is withdrawn.

### ***Claims***

Applicant's amendments to the claims, filed 1/30/2007, are acknowledged. The amendment cancels claims 1-24 and adds new claims 25-38.

Thus, claims 25-38 are pending and subject to restriction as follows.

### ***Election/Restrictions***

Applicant's election, without traverse, of Group I, drawn to a bioinformatically detectable isolated oligonucleotide, which anneals to a portion of a mRNA transcript of target gene, in the reply filed on 1/30/07 is acknowledged.

Also acknowledged is Applicant's election with traverse of SEQ ID NO:10,068,308.

Applicant's election of target gene EGFR (SEQ ID NO:783,894) is moot in view of the amendment to the claims, which currently do not recite a target gene.

In traversing the requirement to a single SEQ ID NO., Applicant cites the Official Gazette Notice of 1996 (Examination of Patent Applications Containing Nucleotide Sequence, 1192 O.G. 68 (November 19, 1996), argues ten sequences constitute a reasonable number for examination purposes absent an exceptional case, and alleges the Examiner has failed to demonstrate that the claimed sequences are an exceptional case necessitating that the number of sequences to be selected be less than ten. Applicant submits that the Examiner is impermissibly disregarding the waiver of 37 C.F.R. §1.141 et seq.

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Applicant is advised the Official Gazette Notice of 1996 and waiver have been rescinded. See the OG Notice of 27 March 2007 (1316 OG 122), which states in part that "Claims to polynucleotide molecules will be considered for independence, relatedness, distinction and burden as for claims to any other type of molecule." Thus, Applicant's arguments are not persuasive. Moreover, the phrase "up to ten" includes one (1), and in view of the complex nature of sequence searching and analysis required to search and examine even one sequence, one sequence is a reasonable number.

The Office decision to rescind the 1996 waiver is based upon the increasing computational, search and examination burden required for the consideration of nucleic acids sequences, and complexity of claims drawn to such, compared to the time of the 1996 waiver (see the statistics cited in the OG Notice). For national applications filed under 35 USC 111(a), polynucleotide molecules will be subject to the standards for requiring a restriction set forth in MPEP Chapter 800 (except for 803.04 which is superseded by this Notice). Polynucleotide molecules will be considered for independence, relatedness, distinction and burden as for any other type of molecule.

Applicant previously claimed several thousand, if not 10s of thousands, unique nucleotide sequences, differing one from the other both structurally and functionally. Polynucleotide molecules having different nucleotide sequences are structurally distinct chemical compounds, having different physical, chemical, and biological properties. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 USC §121.

The requirement is still deemed proper and is therefore made FINAL.

***Notice of non-responsive reply***

Applicant's reply filed 1/30/2007 is not fully responsive to the requirement mailed 11/22/2006.

Claims 25-38, as presented on 1/30/07, continue to recite severally different structurally and functionally distinct nucleotide sequences. In particular, see claims 26, 27, 30, and 31. Applicant has not elected a single sequence among the recited sequences, as required. The nucleic acids claimed therein are considered to represent independent or distinct inventions for the same reasons set forth in the Requirement mailed 11/22/06 (pp. 6-9). Pursuant to 35 U.S.C. 121, Applicant is required to elect one sequence from claims 26, 27, 30, and 31 for prosecution on the merits with the elected group.

***Conclusion***

Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/

Examiner, AU1635

January 12, 2008